K081318

JUN - 9 2008

OneTouch® Zoom™ Diabetes Management Program

510(k) Summary

Sponsor
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035 U.S.A.

Correspondent
Primary 510(k) Contact:
Frank Peralta
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Phone: 408.942.3588
e-mail: fperalta@lfsus.jnj.com

Alternate 510(k) Contact:
Mary Ellen Holden
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Phone: 408.942.3589
E-mail: mholden@lfsus.jnj.com

Device Name and Classification

OneTouch® Zoom™ Diabetes Management Program
Common name: Glucose test system
Classification:
OneTouch® Zoom™ Diabetes Management Program-
a Class II device
(21 CFR § 862.1345)

Product Description

The OneTouch® Zoom™ Diabetes Management Program is a web-based application that is designed to retrieve blood glucose data from the Microsoft® HealthVault™ and provide trending and reports in order to assist people with diabetes management.

The program also includes a stand-alone software driver, branded as OneTouch® Meter Drivers for use with Microsoft® HealthVault™ that downloads blood glucose data from Lifescan Brand blood glucose meters with data management capabilities to Microsoft® HealthVault™ Connection Center, which subsequently upload the data to the user's online Microsoft® HealthVault™ account.

The OneTouch® Zoom™ Diabetes Management Program is a .NET based client/server application that runs on Windows 2003 server and supports Internet Explorer 6.0 and higher on the client side.

The OneTouch® Meter Drivers for use with Microsoft® HealthVault™ run on Windows XP Service Pack 2 and Windows Vista platforms.

Predicate Device

OneTouch® Diabetes Management Software

Intended Use

The ONE TOUCH® Zoom™ Diabetes Management Program is intended for use in home and clinical settings to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to LifeScan blood glucose monitoring systems with data management capabilities.

Comparison to Predicate Device

The modifications to the device encompass:

- **Reports:** a reduction in the number of reports from eleven to two.
- **Data Storage:** a change in data storage on a local database stored on the user's PC to a remote database hosted by Microsoft Corporation, connected via the Internet.

There has been no change to the intended use, operating principle, functionality, or material composition of the device.

Technological Characteristics

There has been no change to the fundamental scientific technology.

Summary of Performance Characteristics

There has been no change to the performance characteristics of the product.

Design Verification testing (including software verification and validation testing) confirmed that the performance, safety, and effectiveness of the OneTouch® Zoom™ Diabetes Management Program was equivalent to that of the predicate device.

Conclusion

The OneTouch® Zoom™ Diabetes Management Program is substantially equivalent to the predicate OneTouch Diabetes Management Software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 9 2008

LifeScan, Inc.
Mr. Frank Peralta
Senior Regulatory Submissions Specialist
1000 Gibraltar Drive
Milpitas, CA, 95035-6312

Re: K081318
Trade/Device Name: OneTouch® Zoom™ Diabetes Management Program
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: May 9, 2008
Received: May 12, 2008

Dear Mr. Peralta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081318

Device Name: **ONE TOUCH® Zoom™ Diabetes Management Program**

Indications for Use:

The ONE TOUCH® Zoom™ Diabetes Management Program is intended for use in home and clinical settings to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to LifeScan blood glucose monitoring systems with data management capabilities.

Prescription Use _____ AND/OR Over-the-Counter Use X
(Per 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081318